

February 19, 1999  
Department of Health and Human Services  
Public Health Service  
National Institutes of Health  
Bethesda, Maryland 20892

The Honorable Henry A. Waxman  
House of Representatives  
Washington, D.C. 20515-0529

Dear Mr. Waxman:

I am writing to provide further information in response to Question 5 in your December 7, 1998, letter. You asked whether there were any situations at the NIH similar to those involving a senior official of the National Institute of Diabetes and Digestive and Kidney Diseases who engaged in an outside activity with a pharmaceutical firm that produces a drug for the treatment of diabetes.

In response to your question, staff in my office who have overall responsibility for our ethics program reviewed documents relating to all approved outside activities for our employees who are involved in the review and award of grants and contracts (our extramural program staff) for activities relating to private sector firms. They reviewed records for the past three years. There are approximately 2,060 employees at the NIH involved with the review and award of grants and contracts. We found that 85 of these employees had received approval for outside activities with the private sector. Because some employees engaged in more than one such activity, 123 separate activities were reviewed.

The review of proposed outside activities often requires difficult decisions involving the nuances of Federal conflict of interest laws and regulations and frequent interpretations of these by the Office of Government Ethics. After completing our review we found only three approved outside activities, involving two employees in our extramural grants administration program, which should not have been approved. These cases appear to be isolated and are not indicative of any wide-spread abuse or inappropriate application of ethics laws and regulations by our staff.

The first case involves a GS-15 supervisory employee, who works in a grants administration program that is responsible for developing a vaccine for the prevention of AIDS. He was paid to participate in a round table discussion with a French corporation in the summer of 1998 to provide advice about the development of a vaccine for the treatment of AIDS. Although this employee was working on the prevention of AIDS and the outside activity involved the development of a vaccine for the treatment of AIDS, we believe that a distinction between the two was an inappropriate boundary, since the underlying science is the same. As a result, the outside activity was so closely related to the duties this scientist performs for NIH that it should not have been approved.

The scientist has been directed to return my compensation he received from this activity, and he will disqualify himself from all official dealings with this corporation for one full year from the date the outside activity ceased.

In the second case, we found that a GS-14 grants administrator engaged in two outside activities with the same pharmaceutical company. On two separate occasions, one in March 1997 and the other in November 1997, the scientist gave paid presentations to a group of physicians on establishing clinical trials in diabetes. He also discussed the NIH Diabetes Prevention Program in these presentations. Both the Government-wide Standards of Ethical Conduct and NIH ethics policy generally prohibit employees from receiving compensation from a source other than the Government for public speaking that relates to the employee's official duties. NIH employees may speak to outside organizations about matters to which they are currently assigned, but they must do so as a part of their official duties. As such, these two

outside activities should not have been approved. This employee has agreed to return the compensation he received from these activities.

NIH is taking steps to deal with these specific cases and to attempt to prevent any future occurrences of a similar nature. With respect to the three activities discussed above, the Directors and senior ethics officials of the Institutes involved were contacted by Office of the Director staff who coordinate the NIH ethics programs. They discussed with the Institute officials their views on why the activities were inappropriate and should not have been approved. Each of these Institutes has been asked to provide a written explanation of the specific actions they will take to ensure that outside activities will only be approved in the future if the proposed activity is clearly permitted by applicable statutes and regulation.

As noted above, matters relating to the ethics rules governing Federal employees are complex and involve interpretation of Federal law and regulation. This review of outside activities between our staff engaged in grants administration and private firms has disclosed only three instances over three years where questionable decisions were made to approve the activities. Given this small number of cases, I believe that you and the public can be assured that our research programs have not been compromised by inappropriate activities. As stated in my earlier letter to you on this subject, public trust is at stake whenever an impropriety occurs, especially in clinical studies. Thus, we will do everything we can to ensure that the public's trust in our research is not misplaced.

I have spoken to all of the Institute and Center Directors about my general concerns regarding inappropriately approved outside activities, and have instructed them to communicate these views to their staff. I have directed in writing that they examine their respective outside activity review procedures and take whatever steps are needed to prevent inappropriate activities from being approved in the future. A copy of my memo to Institute and Center Directors and senior Office of the Director staff on this issue is enclosed for your information.

In addition, the NIH Office of Human Resource Management prepared a summary of the guidelines for outside activities. This document will be widely circulated within NIH. We are also reviewing the NIH Ethics Program to be certain that our guidelines provide managers, scientists, and other activities they can and, more importantly, what types they cannot perform. Furthermore, the U.S. Office of Government Ethics will be conducting a regularly scheduled ethics program review of three Institutes beginning in April 1999. We will immediately implement any further actions this review may identify.

I appreciate your interest in this matter. I intend to see that the NIH maintains a strong ethics program, and that our employees engage only in properly approved outside activities and comply with applicable ethics laws while conducting these activities.

Sincerely,

Harold Varmus, M.D.  
Director